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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/508,435 03/13/00 ASADA

H 00177/530985

EXAMINER

HM12/0703

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WASHINGTON DC 20006

NOLAN, P.	
ART UNIT	PAPER NUMBER

1644

DATE MAILED:

07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**09/508,435**

Applicant(s)  
**Asada et al.**

Examiner  
**Patrick Nolan**

Art Unit  
**1644**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:

- ☐ Certified copies of the priority documents have been received.
- ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
- ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

Serial Number: 09/508,435

Art Unit: 1644

**Part III DETAILED ACTION**

1. Claims 1-8 are pending.

2. Applicant is notified that references AJ and AK on the IDS submitted on 3-13-2000 and reference AK on the IDS submitted 7-11-2000 have not been considered because they were not in English.

Applicant is requested to submit English translations of these documents as well as a certified English translation of the Japanese Priority document JP 246684.

3. Claims 1-8 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 recited the phrase "characterized in", it is unclear what is meant by the term because in scientific parlance characterization may imply one or more physical steps or procedures to identify a product, and the physical steps are not recited in the claims. Furthermore the scope of the term "characterized" is unclear, is it open or closed? Correction is required.

Claims 2 and 3 recite "by the amino acids Nos. 27-102 of SEQ ID NO: 1", when SEQ ID NO. 1 is a nucleic acid sequence. Correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Hunt et al. (U).

Hunt et al., teaches an immunoassay specific for gamma-BNP, also known as Pro-BNP, wherein said immunoassay uses a first antibody reactive with human alpha-BNP, also known as mature or BNP-32, and a second antibody reactive with PreProBNP or gamma-BNP and not reactive with alpha-BNP (see Table 1 and Material and Methods in particular). The gamma-BNP antibody was made from an oligopeptide which was not part of alpha-BNP so it would inherently not bind alpha-BNP and it would inherently bind amino acid sequence shown by amino acid residues 27-102 of SEQ ID NO. 1 because the antibody was made from residues 27-39 of SEQ ID NO. 2, which is the amino acid sequence of SEQ ID NO.1 which is a nucleic acid sequence. Lastly Hunt et al., teaches that the antibodies are labeled with a radioactive isotope.

Serial Number: 09/508,435

Art Unit: 1644

The prior art teachings anticipate the claimed invention.

**Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 6-8 are rejected under 35 U.S.C. § 103 as being unpatentable over Hunt et al. (U).

Hunt et al., has been discussed supra.

The claimed invention differs from the prior art teachings only by the recitation of a kit. However, One skilled in the art would have recognized the usefulness of supplying an antibody BNP test kit for use in diagnostic assays. Test kits are compounds packaged for the convenience of the practitioner and are conventionally made to reproducibly obtain results under test conditions and it is conventional to assemble all necessary reagents, including antibodies, buffers and standards for the convenience of the practitioner and commercial expediency. Furthermore, the preamble reciting "A kit for ..." does not convey any patentable weight to the actual components of the kit itself.

Therefore, it would have been prima facie obvious to one of

Serial Number: 09/508,435

Art Unit: 1644

ordinary skill in the art at the time the invention was made to assay for the presence of BNP as taught by Hunt et al., and package the assay as a kit with the expectation that kits allow for ease and commercial reproducibility of known assays..

6. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants cooperation is requested in correcting any errors of which applicant may become aware of in the specification.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is (703) 305-1987. The examiner can normally be reached on Monday through Friday from 8:30 am to 4:30 pm.

8. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 305-3973. The FAX number for our group, 1644, is (703) 305-7939. Any inquiry of a general nature relating to the status of this application or proceeding should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

*Patrick J. Nolan*

Patrick J. Nolan, Ph.D.  
Primary Examiner, Group 1640  
July 2, 2001